



## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Office of the Secretary

Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19; Correction

**ACTION:** Notice, correction

**SUMMARY:** This document clarifies a term that appeared in the “Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19,” including in the final notice published in the **Federal Register** on September 14, 2021, entitled “Ninth Amendment to Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19.” Specifically, this document supplements the references to the Advisory Committee on Immunization Practices (ACIP) with references to the Centers for Disease Control and Prevention (CDC). This change is being made to clarify that what are commonly referred to as “ACIP recommendations” and “ACIP standard immunization schedules” are in fact recommendations and schedules made by the CDC after consultation with ACIP. The addition of “CDC” is also intended to recognize coverage of recommendations issued directly by the CDC. This clarification also applies to related guidance and opinions.

**DATES:** This correction is applicable September 30, 2021.

**FOR FURTHER INFORMATION CONTACT:** L. Paige Ezernack, Office of the Assistant Secretary for Preparedness and Response, Office of the Secretary, Department of Health and Human Services, 200 Independence Avenue SW, Washington, DC 20201; 202-260-0365, [paige.ezernack@hhs.gov](mailto:paige.ezernack@hhs.gov).

### Corrections

Corrections to technical errors that appeared in sections V(d) and (h) and XII of the final notice published in the **Federal Register** on September 14, 2021 at 86 FR 51160 entitled “Ninth Amendment to Declaration Under the Public Readiness and Emergency Preparedness Act for

Medical Countermeasures Against COVID-19. These corrections are made to clarify that when the term Advisory Committee on Immunization Practices (ACIP) schedule or recommendation is used in the declaration, that refers to recommendations made to the Centers for Disease Control and Prevention (CDC) by the ACIP in its advisory role under the Federal Advisory Committee Act. Such recommendations are taken into consideration when the CDC issues its recommendations, as adopted by the CDC Director. These have historically been published in CDC's *Morbidity and Mortality Weekly Report* under the title "ACIP recommendations." The term "CDC" is added throughout the declaration whenever referring to ACIP recommendations or schedules to also recognize coverage of recommendations issued directly by the CDC.

Subsection V(d) is clarified to read:

(d) A State-licensed pharmacist who orders and administers, and pharmacy interns and qualified pharmacy technicians who administer (if the pharmacy intern or technician acts under the supervision of such pharmacist and the pharmacy intern or technician is licensed or registered by his or her State board of pharmacy),<sup>1</sup> (1) vaccines that the CDC/ACIP recommend<sup>2</sup> to persons ages three through 18 according to CDC's/ACIP's standard immunization schedule or (2)

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<sup>1</sup> Some states do not require pharmacy interns to be licensed or registered by the state board of pharmacy. As used herein, "State-licensed or registered intern" (or equivalent phrases) refers to pharmacy interns authorized by the state or board of pharmacy in the state in which the practical pharmacy internship occurs. The authorization can, but need not, take the form of a license from, or registration with, the State board of pharmacy. Similarly, states vary on licensure and registration requirements for pharmacy technicians. Some states require certain education, training, and/or certification for licensure or registration; others either have no prerequisites for licensure or registration or do not require licensure or registration at all. As used herein, to be a "qualified pharmacy technician," pharmacy technicians working in states with licensure and/or registration requirements must be licensed and/or registered in accordance with state requirements; pharmacy technicians working in states without licensure and/or registration requirements must have a CPhT certification from either the Pharmacy Technician Certification Board or National Healthcareer Association. See [Guidance for PREP Act Coverage for Qualified Pharmacy Technicians and State-Authorized Pharmacy Interns for Childhood Vaccines, COVID-19 Vaccines, and COVID-19 Testing](https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents//prep-act-guidance.pdf), OASH, Oct. 20, 2020 at 2, available at <https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents//prep-act-guidance.pdf> (last visited Jan. 24, 2021).

<sup>2</sup> Where the term CDC/ACIP recommendations, standard immunization schedules, or similar language is used, this includes both direct CDC recommendations as well as recommendations adopted by the CDC Director after recommendation by ACIP, which are commonly referred to as ACIP recommendations or schedules.

seasonal influenza vaccine administered by qualified pharmacy technicians and interns that the CDC/ACIP recommend to persons aged 19 and older according to CDC's/ACIP's standard immunization schedule; or (3) FDA authorized or FDA licensed COVID -19 vaccines to persons ages three or older. Such State-licensed pharmacists and the State-licensed or registered interns or technicians under their supervision are qualified persons only if the following requirements are met:

- i. The vaccine must be authorized, approved, or licensed by the FDA;
- ii. In the case of a COVID–19 vaccine, the vaccination must be ordered and administered according to CDC's/ACIP's COVID–19 vaccine recommendation(s);
- iii. In the case of a childhood vaccine, the vaccination must be ordered and administered according to CDC's/ACIP's standard immunization schedule;
- iv. In the case of seasonal influenza vaccine administered by qualified pharmacy technicians and interns, the vaccination must be ordered and administered according to CDC's/ACIP's standard immunization schedule;
- v. In the case of pharmacy technicians, the supervising pharmacist must be readily and immediately available to the immunizing qualified pharmacy technician;
- vi. The licensed pharmacist must have completed the immunization training that the licensing State requires for pharmacists to order and administer vaccines. If the State does not specify training requirements for the licensed pharmacist to order and administer vaccines, the licensed pharmacist must complete a vaccination training program of at least 20 hours that is approved by the Accreditation Council for Pharmacy Education (ACPE) to order and administer vaccines. Such a training program must include hands on injection technique, clinical evaluation of indications and contraindications of vaccines, and the recognition and treatment of emergency reactions to vaccines;
- vii. The licensed or registered pharmacy intern and qualified pharmacy technician must complete a practical training program that is approved by the ACPE. This training

program must include hands-on injection technique, clinical evaluation of indications and contraindications of vaccines, and the recognition and treatment of emergency reactions to vaccines;

- viii. The licensed pharmacist, licensed or registered pharmacy intern and qualified pharmacy technician must have a current certificate in basic cardiopulmonary resuscitation;<sup>3</sup>
- ix. The licensed pharmacist must complete a minimum of two hours of ACPE-approved, immunization-related continuing pharmacy education during each State licensing period;
- x. The licensed pharmacist must comply with recordkeeping and reporting requirements of the jurisdiction in which he or she administers vaccines, including informing the patient's primary-care provider when available, submitting the required immunization information to the State or local immunization information system (vaccine registry), complying with requirements with respect to reporting adverse events, and complying with requirements whereby the person administering a vaccine must review the vaccine registry or other vaccination records prior to administering a vaccine;
- xi. The licensed pharmacist must inform his or her childhood vaccination patients and the adult caregiver accompanying the child of the importance of a well-child visit with a pediatrician or other licensed primary care provider and refer patients as appropriate; and

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<sup>3</sup> This requirement is satisfied by, among other things, a certification in basic cardiopulmonary resuscitation by an online program that has received accreditation from the American Nurses Credentialing Center, the ACPE, or the Accreditation Council for Continuing Medical Education. The phrase "current certificate in basic cardiopulmonary resuscitation," when used in the September 3, 2020 or October 20, 2020 OASH authorizations, shall be interpreted the same way. See [Guidance for Licensed Pharmacists and Pharmacy Interns Regarding COVID-19 Vaccines and Immunity under the PREP Act](https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents//licensed-pharmacists-and-pharmacy-interns-regarding-covid-19-vaccines-immunity.pdf), OASH, Sept. 3, 2020, available at <https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents//licensed-pharmacists-and-pharmacy-interns-regarding-covid-19-vaccines-immunity.pdf> (last visited Jan. 24, 2021); [Guidance for PREP Act Coverage for Qualified Pharmacy Technicians and State-Authorized Pharmacy Interns for Childhood Vaccines, COVID-19 Vaccines, and COVID-19 Testing](https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents//prep-act-guidance.pdf), OASH, Oct. 20, 2020, available at <https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents//prep-act-guidance.pdf> (last visited Jan. 24, 2021).

- xii. The licensed pharmacist, the licensed or registered pharmacy intern and the qualified pharmacy technician must comply with any applicable requirements (or conditions of use) as set forth in the CDC COVID–19 vaccination provider agreement and any other federal requirements that apply to the administration of COVID– 19 vaccine(s).

Section V(h) is clarified to read:

(h) The following healthcare professionals and students in a healthcare profession training program subject to the requirements of this paragraph:

1. Any midwife, paramedic, advanced or intermediate emergency medical technician (EMT), physician assistant, respiratory therapist, dentist, podiatrist, optometrist or veterinarian licensed or certified to practice under the law of any state who prescribes, dispenses, or administers COVID-19 vaccines that are Covered Countermeasures under section VI of this Declaration in any jurisdiction where the PREP Act applies in association with a COVID-19 vaccination effort by a State, local, Tribal or territorial authority or by an institution in which the COVID-19 vaccine covered countermeasure is administered;
2. Any physician, advanced practice registered nurse, registered nurse, practical nurse, pharmacist, pharmacy intern, midwife, paramedic, advanced or intermediate EMT, respiratory therapist, dentist, physician assistant, podiatrist, optometrist, or veterinarian who has held an active license or certification under the law of any State within the last five years, which is inactive, expired or lapsed, who prescribes, dispenses, or administers COVID-19 vaccines that are Covered Countermeasures under section VI of this Declaration in any jurisdiction where the PREP Act applies in association with a COVID-19 vaccination effort by a State, local, Tribal or territorial authority or by an institution in which the COVID-19 vaccine covered countermeasure is administered, so long as the license or certification was active and in good standing prior to the date it went inactive, expired or lapsed and was not revoked by the licensing authority, surrendered while under suspension, discipline or investigation by a licensing authority or

surrendered following an arrest, and the individual is not on the List of Excluded

Individuals/Entities maintained by the Office of Inspector General;

3. Any medical, nursing, pharmacy, pharmacy intern, midwife, paramedic, advanced or intermediate EMT, physician assistant, respiratory therapy, dental, podiatry, optometry or veterinary student with appropriate training in administering vaccines as determined by his or her school or training program and supervision by a currently practicing healthcare professional experienced in administering intramuscular injections who administers COVID-19 vaccines that are Covered Countermeasures under section VI of this Declaration in any jurisdiction where the PREP Act applies in association with a COVID-19 vaccination effort by a State, local, Tribal or territorial authority or by an institution in which the COVID-19 vaccine covered countermeasure is administered;

Subject to the following requirements:

- i. The vaccine must be authorized, approved, or licensed by the FDA;
- ii. Vaccination must be ordered and administered according to CDC's/ACIP's COVID-19 vaccine recommendation(s);
- iii. The healthcare professionals and students must have documentation of completion of the CDC COVID-19 Vaccine Training Modules and, if applicable, such additional training as may be required by the State, territory, locality, or Tribal area in which they are prescribing, dispensing, or administering COVID-19 vaccines;
- iv. The healthcare professionals and students must have documentation of an observation period by a currently practicing healthcare professional experienced in administering intramuscular injections, and for whom administering vaccinations is in their ordinary scope of practice, who confirms competency of the healthcare provider or student in preparation and administration of the COVID-19 vaccine(s) to be administered and, if applicable, such additional training as may be required by the State, territory, locality, or

Tribal area in which they are prescribing, dispensing, or administering COVID-19 vaccines;

- v. The healthcare professionals and students must have a current certificate in basic cardiopulmonary resuscitation;<sup>4</sup>
- vi. The healthcare professionals and students must comply with recordkeeping and reporting requirements of the jurisdiction in which he or she administers vaccines, including informing the patient's primary-care provider when available, submitting the required immunization information to the State or local immunization information system (vaccine registry), complying with requirements with respect to reporting adverse events, and complying with requirements whereby the person administering a vaccine must review the vaccine registry or other vaccination records prior to administering a vaccine; and
- vii. The healthcare professionals and students comply with any applicable requirements (or conditions of use) as set forth in the CDC COVID-19 vaccination provider agreement and any other federal requirements that apply to the administration of COVID- 19 vaccine(s).

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<sup>4</sup> This requirement is satisfied by, among other things, a certification in basic cardiopulmonary resuscitation by an online program that has received accreditation from the American Nurses Credentialing Center, the ACPE, or the Accreditation Council for Continuing Medical Education. The phrase "current certificate in basic cardiopulmonary resuscitation," when used in the September 3, 2020 or October 20, 2020 OASH authorizations, shall be interpreted the same way. See [Guidance for Licensed Pharmacists and Pharmacy Interns Regarding COVID-19 Vaccines and Immunity under the PREP Act, OASH](https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents//licensed-pharmacists-and-pharmacy-interns-regarding-covid-19-vaccines-immunity.pdf), Sept. 3, 2020, available at <https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents//licensed-pharmacists-and-pharmacy-interns-regarding-covid-19-vaccines-immunity.pdf> (last visited Jan. 24, 2021); [Guidance for PREP Act Coverage for Qualified Pharmacy Technicians and State-Authorized Pharmacy Interns for Childhood Vaccines, COVID-19 Vaccines, and COVID-19 Testing, OASH](https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents//prep-act-guidance.pdf), Oct. 20, 2020, available at <https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents//prep-act-guidance.pdf> (last visited Jan. 24, 2021).

Section XII is clarified to read:

“Liability protections for all Covered Countermeasures administered and used in accordance with the public health and medical response of the Authority Having Jurisdiction, as identified in Section VII(b) of this Declaration, begin with a Declaration of Emergency as that term is defined in Section VII (except that, with respect to qualified persons who order or administer a routine childhood vaccination that CDC/ACIP recommends to persons ages three through 18 according to CDC’s/ACIP's standard immunization schedule, liability protections began on August 24, 2020), and last through (a) the final day the Declaration of Emergency is in effect, or (b) October 1, 2024, whichever occurs first.” This amendment does not change effective dates under Section XII.

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